K014224
PAGE 1 OF 1

JAN 2 3 2002

510 (K) SUMMARY

Manufacturer:	VidaMed, Inc. 46107 Landing Parkway Fremont, CA 94538 510-492-4900 510-492-4999 (fax)
Contact	Dr. Yi Chen, RAC
Date of Preparation	December 21, 2001
Trade Name	Precision™ Plus TUNA® Office System
Common Name	Electrosurgical Generator and Accessories
Classification Name	Electrosurgical Cutting and Coagulation Devices and Accessories
Substantial Equivalence	Precision™ TUNA® Office System PROVu™ TUNA® System
Product Code	GEI KNS
21 CFR Section	878.4400 876.4300
Device Description	The Precision™ Plus TUNA® Office System consists of a RF Generator, a sterile single-use Cartridge attached to a reusable Handle, a reusable Telescope, a single-use Return Electrode, a sterile single-use Tubing set, and other accessories.
Indication for Use	The Precision™ Plus TUNA® Office System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.
Technology Characteristics	The Precision™ Plus TUNA® Office System delivers low levels of 460 kHz RF energy up to 15 W from each of the 2 needles directly into prostatic tissue to produce a localized necrotic lesion to treat the symptoms associate with BPH. Each lesion takes 3.0 minutes.
Test Summary	Lesion equivalence between the Precision™ Plus TUNA® Office System and the PROVu™ TUNA® System has been established through lab bench testing.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2002

Dr. Yi Chen, R.A.C.
Director of Regulatory Affairs
and Quality Assurance
VIDAMED®
46107 Landing Pkwy
FREMONT CA 94538

Re: K014224
Trade/Device Name: Precision™ Plus TUNA® Office System with Model 7900 RF Generator, Model 6900 Cartridge, and Model 6198 Handle
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KNS
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: 79 GEI
Dated: December 21, 2001
Received: December 26, 2001

Dear Dr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510 (k) Number (if known): K014224

Device Name: Precision™ Plus TUNA® Office System

Indications For Use:

The Precision™ Plus TUNA® Office System is indicated for use in the treatment of symptoms due to urinary outflow obstruction secondary to Benign Prostatic Hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014224